K073219

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5. 510(k) Summary Statement

Submitter: American Medical Systems (AMS)
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APR 10 2008

Contact Person: Mona Inman

Device Common Name: Surgical Mesh

Device Trade Name: WMT Collagen Dermal Matrix

Device Classification Name: Surgical Mesh (FTM)

Predicate Devices: AMS Collagen Dermal Matrix, marketed as "InteXen LP" (K050445),
RESTORE Soft Tissue Implant (K071016),
OrthADAPT FX (K071065)

Device Description
The WMT Collagen Dermal Matrix is a sterile, non-perforated processed porcine collagen dermal matrix.

Indications for Use

The WMT Collagen Dermal Matrix is intended to reinforce soft tissue where weakness exists, specifically, for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, and other tendons. The WMT Collagen Dermal Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear, and suture or bone anchors used to attach the tissue to the bone, provide biomechanical strength for the tendon repair.

Comparison to Predicate Devices
The three predicate devices are biological-derived surgical mesh used in tissue repair and tissue reinforcement. Mechanical testing characterized the suitability of the subject device, WMT Collagen Dermal Matrix, in orthopedic applications, and compared the test results of both OrthADAPT™ FX and RESTORE® predicate devices, surgical meshes which are currently indicated for orthopedic applications. All predicate surgical meshes are provided sterile and are indicated for single use.

Supporting Information
Substantial equivalency was supported by information from previously cleared devices, and new bench testing comparing predicate devices and the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

American Medical Systems
% Ms. Mona Inman
10700 Bren Road West
Minnetonka, Minnesota 55343

APR 10 2008

Re: K073219
Trade/Device Name: WMT Collagen Dermal Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: April 1, 2008
Received: April 2, 2008

Dear Ms. Inman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073219

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: WMT Collagen Dermal Matrix

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Prescription Use___X___ AND/OR Over-The Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073219